TERUMO

K080774

APR 17 2008

***Submitter Information:***

This submission was prepared in March 2008 by:

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This submission was prepared for:

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Manufacturer/Sterilizer
150 Maimaigi-cho, Fujinomiya City
Shizuoka Pref. Japan 418-0015
Registration #9681834

***Device Names/Classifications:***

| Proprietary Name | Classification Name | Common Name |
|---|---|---|
| Capiox® SP Pump | Non-Roller, Cardiopulmonary Bypass Blood Pump (Code: KFM) | Centrifugal Pump |

***Predicate Device:***

The device submitted in this 510(k) maintains characteristics that are *substantially equivalent* in intended use, design, technology/principles of operation, materials and specifications to the following devices:

- Terumo's Capiox® SP Pump – K012209 and K962981
- Medtronic BPX-80 Bio-Pump® - K973011

***Substantial Equivalence Comparison:***

***Intended Use***

The Capiox® SP Pump is used to facilitate blood flow in the extracorporeal circuit for circulatory support during extracorporeal circulation for up to 6 hours.

The Capiox® SP Pump is a sterile, single use device. The pump is a non-roller type pump that couples magnetically to, and is magnetically driven by the BioMedicus BioConsole Models 540, 550 and 560 via the pumphead adaptor.

*Comparison to Predicate*: The intended use of the Capiox® SP Pump remains essentially unaffected by the change proposed in this application. This new application, upon FDA clearance, allows the additional indication that the Capiox® SP Pump can be used in conjunction with the BioMed 560 console – in addition to the current indications that it can be used with the BioMed 540 and 550 consoles. Similarly, the Medtronic BPX-80 Bio-Pump® is indicated as a circulatory support device that is intended to pump blood through a bypass circuit during extracorporeal bypass procedures.

***Duration of Use***

The Capiox® SP Pump is indicated for use in procedures lasting not more than 6 hours in duration.

*Comparison to Predicate*: There will be no differences noted in the 6-hour duration as a result of the added indication that the product can be used with the BioMed 560 console. Similarly, the Medtronic BPX-80 Bio-Pump® is also indicated for usage not to exceed 6 hours.

***Labeling***

Terumo Corporation currently provides labeling and adequate instructions for use with the Capiox® SP Pump. The instructions for use (IFU) are provided with each delivery of the product to the user facility.

*Comparison to Predicate*: The instructions manual for the Capiox® SP Pump will be updated to indicate that the device can be used with the BioMed 560 console. No additional significant changes are planned for the instructions or other labeling.

***Principles of Operation and Technology***

The Capiox® SP Pump performs it's function using centrifugal force technology. As blood enters the device via the blood inlet port, centrifugal forces created by the pump activity will propel the blood through the pump and out of the device via a blood outlet port.

*Comparison to Predicate*: The existing principles of operation and the technology employed by the Capiox® SP Pump remain unaffected by the added product indication. The employed technology utilized by the Medtronic BPX-80 Bio-Pump® is essentially identical to that of the Terumo device. Both devices are "fed" via gravity drainage of blood into the device – followed by a pumping device that creates circulation throughout the bypass circuit. Both devices rely upon a console drive, as well as centrifugal force.

***Design and Materials***

The design and materials of the Capiox® SP Pump is such that the device meets it's stated intended use – and provides an acceptable level of performance and safety to the patient. The device is a hardshell housing that contains a blood compartment (blood chamber) and a non-blood compartment (rear chamber). Within the blood chamber is a rotating impeller-type component that imparts centrifugal force upon blood as it enters the device. These centrifugal forces move the blood out of the device via the outlet port – and propel the blood through the bypass circuit.

*Comparison to Predicate:* The design and manufacturing of the Capiox® SP Pump are not changing as a result of the added product indication. Further, the materials used in the manufacturing of the Capiox® SP Pump are not changing as a result of the added product indication. The proposed change included in this application is to add a new indication. There are no design changes, nor are there any material changes included in this application. When compared to the materials used in the predicate Medtronic BPX-80 Bio-Pump®, it is noted that there are differences between the two devices with the most significant difference being the coating materials that are applied to the blood contacting surfaces. The Terumo device is coated with polymethoxyethyl acrylate, whereas the Medtronic device is covered with Trillium® or Carmeda® coating. While these surfactants may differ chemically from Terumo's X-Coating, the safety and effectiveness or each of these materials are well-recognized and have been extensively used in medical devices. Such noted differences are not thought to raise previously unrecognized issues of safety or effectiveness.

***Performance Evaluations***

Clinical studies involving patients are not necessary to demonstrate substantial equivalence of the subject device to the predicate device. Performance studies for the intent of demonstrating safe and effective use of the Capiox® SP Pump with the BioMed 560 console is demonstrated with the following *in-vitro* performance evaluations:

- Pump Load (Pressure differential Inlet v. Outlet) testing (comparative testing v. predicate)
- 9-hour Durability Testing - (attribute evaluation / not compared to predicate)
- BioMed Flow Probe & Pressure Meter Accuracy testing - (comparative testing v. predicate)
- Decoupling (separation from drive system) testing - (attribute evaluation / not compared to predicate)

*Comparison to predicate:* The performance of the Capiox® SP Pump with the added indication for use with the BioMed 560 console is equivalent to the performance of the predicate Terumo device and the Medtronic BPX-80 Bio-Pump® when used on the 560 console. No significant differences in performance were noted.

***Conclusion:***

In summary, Terumo deems the Capiox® SP Pump with the added indication for use with the BioMed 560 console as *substantially equivalent* to the established predicates with respect to intended use, duration of use, design, materials, principles of operation, performance and specifications. The only noted difference between the predicate and the proposal indicated in this application is that the Capiox® SP Pump can be used with a BioMed 560 console.

***Substantial Equivalence Statement:***
The Capiox® SP Pump and the established predicates are substantially equivalent in intended use, principles of operation and technology, design and materials, and performance.

***Additional Safety Information:***

- Sterilization conditions have been validated in accordance with AAMI guidelines to provide a Sterility Assurance Level (SAL) of $10^{-6}$.

- Terumo maintains biocompatibility studies for all blood-contacting materials as recommended in the FDA General Program Memorandum #G95-1 (5/1/95): Use of International Standard ISO 10993, "Biological Evaluation of Medical Devices – Part 1: Evaluation and Testing." [External Communicating Devices, Circulating Blood, Limited Exposure (≤ 24 hours) Contact Duration]. The blood contacting materials are considered to be biocompatible.

- The polymer coating material that is applied to the blood-contacting surfaces of the devices have been evaluated in an *in-vivo* animal study for previous devices submitted to FDA for marketing clearance. No adverse conditions have been noted.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

APR 17 2008

Terumo Cardiovascular Systems Corporation
c/o Mr. Garry A. Courtney
Regulatory Management
125 Blue Ball Road
Elkton, MD 21921

Re: K080774
Capiox® SP Pump (with or without X-Coating)
Regulation Number: 21 CFR 870.4360
Regulation Name: Nonroller-type cardiopulmonary bypass pump
Regulatory Class: Class III
Product Code: KFM
Dated: March 14, 2008
Received: March 19, 2008

Dear Mr. Courtney:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.
This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Center for Devices and Radiological Health's (CDRH's) Office of Compliance at (240) 276-0120. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding postmarket surveillance, please contact CDRH's Office of Surveillance and Biometric's (OSB's) Division of Postmarket Surveillance at 240-276-3474. For questions regarding the reporting of device adverse events (Medical Device Reporting (MDR)), please contact the Division of Surveillance Systems at 240-276-3464. You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (240) 276-3150 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Bram D. Zuckerman, M.D.
Director
Division of Cardiovascular Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

TERUMO

**SECTION 4**
**Indications for Use**

**510(k) Number (if known):** K080774

**Device Name: CAPIOX® SP Pump**

## Indications For Use:

The Capiox® SP Pump is used to facilitate blood flow in the extracorporeal circuit for circulatory support during extracorporeal circulation for up to 6 hours.

Note: The Capiox® SP Pump is a sterile, single use device. The pump is a non-roller type pump that couples magnetically to, and is magnetically driven by the BioMedicus BioConsole Models 540, 550 and 560 via the pumphead adaptor.

Prescription Use ___XX___ OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (Part 21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE) 8/14/2008

Donna R. Vochniak
(Division Sign-Off)
Division of Cardiovascular Devices

510(k) Number K080774